App. No. 10/521,234
Office Action Dated July 27, 2007

REMARKS

Favorable reconsideration is respectfully requested in view of the above amendments and following remarks. Applicants appreciate the courtesy shown by the Examiner in discussing this case with Applicants' representative on November 26, 2007. The discussions of the interview are reflected in the following remarks.

Claims 10 and 15 have been amended. Claim 10 has been amended editorially. Claim 15 has been amended to incorporate the subject matter in previous claim 9. Accordingly, Applicants respectfully submit that the amendment should be entered.

The limitation in claim 15 concerning the sulfonic acid compound being at least one selected from the group consisting of dodecylbenzenesulfonic acid sodium salt, lithium lauryl sulfate, 4-aminoazobenzene-4'-sulfonic acid sodium salt, 4-amino-4'-nitrostilbene-2,2'-disulfonic acid disodium salt, 4,4'-diazidostilbene-2,2'-disulfonic acid disodium salt, N-cyclohexyl-2-aminoethane sulfonic acid, N-cyclohexyl-3-aminopropane sulfonic acid, N-cyclohexyl-2-hydroxy-3-aminopropane sulfonic acid, piperazine-1,4-bis(2-ethane sulfonic acid) and bathophenanthroline sulfonic acid is supported for example by previous claim 9 and page 3, lines 30-37 of the specification. Claim 9 has been canceled without prejudice or disclaimer. No new matter has been added. Claims 8 and 10-15 are pending.

Claim rejections - 35 U.S.C. § 112

Claim 15 has been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The rejection is rendered moot, as the questioned limitation in claim 15 has been removed. Applicants do not concede the correctness of the rejection.

Withdrawal of the rejection is respectfully requested.

Claim rejections - 35 U.S.C. § 102

Claims 8 and 12-15 are rejected under 35 U.S.C. 102(e) a being anticipated by EP 1 002874 (Komori et al.). The rejection is rendered moot, as the subject matter in claim 9 has been incorporated into claim 15. Claims 8 and 12-14 depend from claim 15. Applicants do not concede the correctness of the rejection.

Withdrawal of the rejection is respectfully requested.

Claim rejections - 35 U.S.C. § 103

Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1002874 (Komori et al.) in view of Clin. Biochem. 1982, Vol. 15, No. 1, pp. 83-88 (Oshiro et al.) and further in view of U.S. Patent No. 6,127,138 (Ishimaru et al.) and further in view of Blood, 1994, Vol. 83, No. 4, pp. 1117-1123 (Johnson et al.) and further in view of U.S. Patent No. 6,790,665 (Yonehara et al.). Applicants respectfully traverse the rejection.

Claim 15 requires treating a sample containing the glycated protein with a protease in the presence of a sulfonic acid compound. Claim 15 further requires the sulfonic acid compound to be at least one selected from the group consisting of dodecylbenzenesulfonic acid sodium salt, lithium lauryl sulfate, 4-aminoazobenzene-4'-sulfonic acid sodium salt, 4-amino-4'-nitrostilbene-2,2'-disulfonic acid disodium salt, 4,4'-diazidostilbene-2,2'-disulfonic acid disodium salt, N-cyclohexyl-2-aminoethane sulfonic acid, N-cyclohexyl-3-aminopropane sulfonic acid, N-cyclohexyl-2-hydroxy-3-aminopropane sulfonic acid, piperazine-1,4-bis(2-ethane sulfonic acid) and bathophenanthroline sulfonic acid. Since these sulfonic acid compounds generally have a high solubility, they can be treated easily even when the concentration of glycated proteins in the sample is high (see page 4, lines 6-9). Moreover, when the protease treatment is conducted in the presence of one or more of the sulfonic acid compounds as required by claim 15, the degradation time is accelerated significantly, thereby allowing a high degradation efficiency. As a result, the accuracy of measurement is improved considerably (see page 16, lines 3-11 for example).

Komori teaches a method of measuring a glycated protein. The method of Komori involves pretreating a hemolyzed sample with a tetrazolium compound, treating the sample with a protease, and then conducting a fructosyl amino acid oxidase (FAOD) treatment. The FAOD treatment step of Komori involves treating the proteolytically degraded glycated protein with FAOD so as to generate hydrogen peroxide. The hydrogen peroxide is then measured by a redox reaction using POD and a color-developing substrate. Komori teaches that examples of the color-developing substrate include a substrate in which trinder's reagent and 4-aminoantipyrine are combined. The reference teaches that in place of aminoantipyrine, vanillin diamine sulfonic acid may be used. However, nothing in the reference teaches or suggests treating a sample containing the glycated protein with a

protease in the presence of one or more sulfonic acid compounds selected from the group as required claim 15 so as to accelerate the degradation reaction. In fact, Komori notes that the FAOD treatment is conducted subsequent to the protease treatment so that the FAOD used may act on the analyte more easily, and if the color-developing substrate is used, the quantity of hydrogen peroxide can be determined by measuring the degree of the color developed. As such, it is abundantly clear that the reference does not teach or suggest using the color-developing substrate other than for color development, and thus is far from suggesting the use of sulfonic acid compounds as required by claim 15 before the FAOD treatment in order to achieve the effects enjoyed by the claim. Accordingly, claim 15 and the dependent claims therefrom are patentable over Komori.

The rejection relies on Oshiro and Yonehara for the use of sodium lauryl sulfate. The rejection's reliance is moot, as claim 15 does not require the use of sodium lauryl sulfate. Accordingly, claim 15 and the dependent claims therefrom are patentable over the references, taken alone or together.

Moreover, Oshiro is directed to using SLS for the measurement of hemoglobin, and fails to teach or suggest measuring specifically the amount of glycated proteins in a sample using protease and FAOD. The reference even notes that the method does not need oxidative agents. Yonehara discloses that the SLS method involves the addition of both SLS and a strong alkali in a sample, and actually discourages the use of such a method since the addition of these reagents influences enzymatic measurement systems, thereby teaching away from claim 15. Accordingly, claim 15 and the dependent claims therefrom are further removed from the references for at least these reasons.

Neither Johnson nor Ishimaru cures the deficiencies of Komori, Oshiro and Yonehara. Although Johnson discloses lowering reducing substances such as glutathione and Ishimaru discloses the use of metalloprotease, the references fail to teach or suggest the use of a sulfonic acid compound selected from the group as required by claim 15 during the protease treatment. Therefore, claim 15 and the dependent claims therefrom are patentable over the references, taken alone or together.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

App. No. 10/521,234
Office Action Dated July 27, 2007

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully submitted,

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. Box 2902
Minneapolis, MN 55402-0902
(612) 455-3800

52835
PATENT TRADEMARK OFFICE

Dated: December 27, 2007

By: _____
Douglas P. Mueller
Reg. No. 30,300